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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/564,481 | 03/07/2006 | Masahiko Kuroda | 2006 0025A | 7350 |
| 513 7590 03/13/2009 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503 | | | | |
| EXAMINER | | | | |
| SALMON, KATHERINE D | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1634 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/13/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/564,481

Applicant(s)

KURODA ET AL.

Examiner

KATHERINE SALMON

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1 and 6-8.
Claim(s) withdrawn from consideration: 4, 5, 10 and 11.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Juliet C Switzer/
Primary Examiner, Art Unit 1634

Continuation of 11: NOTE: The reply filed on 2/27/2009 acknowledges the telephone interview of 2/18/2009.

The reply asserts that the amendments to the claims have overcome the 35 USC 112/Enablement issues regarding the unpredictability of correlations to diagnosis of "any endometriosis related disease" and "any subject" (p. 5 last 2 full paragraph). The reply asserts that the claims as amended are directed towards measuring histamine releasing factor from menstrual blood of a patient in order to indicate endometriosis or risk of endometriosis (p. 5 last paragraph). The reply asserts that Figure A of the 37 CFR 1.132 declaration submitted 7/3/2008 shows that expression levels of HRF in menstrual blood from endometriosis patients were statistically significantly higher than the HRF gene expression in menstrual blood of normal subjects (p. 5 last paragraph and p. 6 1st paragraph).

These arguments have been fully reviewed but have not been found fully persuasive.

The examiner acknowledges that the amendments to the claims overcome the unpredictability issues involving "any endometriosis related disease" and "any subject".

The reply asserts that the disclosure in the 37 CFR 1.132 provides a statistically significant correlation. It is noted that the 37 CFR 1.132 was addressed in the final rejection in view of the limitations of the claims which were pending at the time of the final rejection. Although the claims have been amended to the scope of the data presented in the 37 CFR 1.132, the 37 CFR 1.132 does not provide any statistical analysis of the data. Although, the 37 CFR 1.132 presents a figure representing the data of HRF expression in menstrual samples, the declaration does not teach any statistical analysis of such expression. Without these statistical calculations the declaration is insufficient to provide a predictable correlation between the expression level of HRF in menstrual blood and endometriosis. As discussed on pages 8-9 of the final rejection, the art (Cheung et al. and Shalon et al) teach that correlations of gene expression and disease are unpredictable and that an assay must present statistically meaningful data to correlations of gene expression and disease (see page 10 paragraph 156 of Shalon et al.). Therefore the 37 CFR 1.132 as filed does not overcome the 35 USC 112/Enablement which is of record.